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Dr. Andrew **Beaulieu**  
Center for Veterinary Medicine

Via Facsimile: 301-594-1830

**Re: Docket No. 99P-4613 (PLEASE INCLUDE IN OFFICIAL DOCKET)**

Dear **Dr. Beaulieu**:

A number of assumptions made regarding protein absorption and digestion were incorrectly applied to Monsanto's **rbGH** approval process. The major flaw in **CVM's** evaluations regarding human safety was based upon the assumption that neither **rbGH** nor IGF-I poses any biological activity when administered orally.

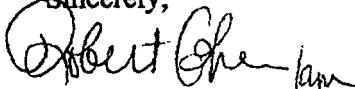
The internal review **from Health Canada** reveals just the opposite. In reviewing the "**90-Day Study**", (that study actually lasted for 180 days) FDA found no evidence of following oral administration of **rbGH**. The Canadian government found something quite **different**. The internal **rbGH** review executive summary revealed:

**"The 90-day subchronic rat study submitted by Monsanto showed that rbST (rbGH) can be absorbed intact in G.I. tract following oral administration of high doses and elicit a primary antigenic response (IgG antibodies). The full immunological, and potential toxicological consequences of this observation were not assessed by HSD. Prior to drawing any definitive conclusions regarding the safety of rbST and IGF-I residues, it is recommended that HSD examines the findings of the study, including pertinent histopathologic data, to confirm the sponsors (Monsanto) contention that they are not relevant to humans"**

It is clear the Canadian Scientists found something that FDA scientists missed. The reason FDA scientists missed this was made clear to me at my April 21, 1995 meeting with FDA -- the key study was never reviewed.

An interesting event occurred on May 11, 1994, it was Health Canada's review for Monsanto's **rbGH**. Reports contained in locked file cabinets were stolen **from** Dr. Hayden's office. **After** she realized **they** were missing and filed a complaint, files were "**re-stuffed** in a sloppy manner" on Monday, May 16, 1994, without her knowledge or approval. A subsequent investigation by the Royal Canadian Mounted Police found no fingerprints and did not identify who accessed the **file** and what documents (if any) were missing. It is my belief that the **second 90-day** portion of the Richard study was surreptitiously removed **from** that file. CVM has that document and its review should be made as part of the review for this petition (Docket No. 99P-4613).

Sincerely,



Robert Cohen

cc: Dr. Linda Tollefson (Fax: 301-594-45 12)  
cc: Dr. Claire Lathers (Fax: 301-594-2297)  
cc: Dr. Marcia Larkins (Fax: 301-594-45 12)

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